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The Need for Independent Expert Advisory Panel to Assess Therapeutic Benefits and Potential Risks of Herbal Products Sold in the U.S.

Good afternoon. I am Mark Blumenthal, founder and executive director of the American Botanical Council (ABC), a nonprofit research and education organization dealing with herbs and medicinal plant products.

I am also the senior editor of *The Complete German Commission E Monographs*, a book of English translations of the official evaluations of herbs by an expert panel commissioned by the German government. This book was ranked second of all publications in medicine and allied health professions in 1998 -- compelling evidence of the need for accurate, authoritative information on the therapeutic uses of herbal products.

ABC has two suggestions for priorities: (1) That FDA establish an independent, external expert advisory panel to deal with botanicals and (2) that FDA respond immediately and directly to the citizens petition submitted to FDA by the European-American Phytomedicines Coalition (EAPC) in July 1992, requesting that well-researched herbs and phytomedicines be deemed *old drugs* under the over-the-counter (OTC) drug review. This week marks the seventh anniversary of this petition to which the agency has declined to respond directly in any meaningful manner. FDA's inaction on this issue sends a mixed message about its sincerity in dealing with herbals as potential OTCs.

Consumers have numerous uses for herbal dietary supplements: to increase energy, stamina, and a sense of well-being; to prevent short or long-term illness; and as substitutes for FDA-approved drugs. However, except for a handful of herbs approved as

ingredients in OTC drugs, most herbal products sold in the U.S. do not, and cannot, carry information on the actual *therapeutic* benefits of their use, regardless of the quantity and quality of research documenting such actions (e.g. treatment, cure, prevention, etc.).

ABC believes that American consumers would benefit from properly documented therapeutic claims on herbal products, without requiring these products to submit to the lengthy and expensive new drug application (NDA) process. ABC also believes that any such review of herbs should be undertaken *without adversely affecting their legal status as dietary supplements under the Dietary Supplement Health and Education Act of 1994 (DSHEA).*

FDA's highest priority – in addition to publishing final regulations for Good Manufacturing Practices (GMPs) for dietary supplements – should be the formation of an independent, external advisory committee to advise the Agency on regulatory issues concerning botanical supplements. Recognizing the lack of internal botanical expertise in the Agency, this committee must be drawn from outside experts. It should consist of scientists familiar with the vast botanical literature, as well as qualified healthcare practitioners from both the conventional and alternative domains who are familiar with the clinical application of botanical preparations, including qualified herbalists. Membership from various industry trade groups, consumer organizations, and professional societies should be considered, possibly on a nonvoting basis.

This panel could cover a variety of regulatory aspects of herbs, especially recommendations to FDA for claims for herbal products under regulations currently provided by the Nutrition Labeling and Education Act of 1990 (NLEA), DSHEA and the OTC Drug Review. Also, it could advise FDA on potential standards that might be required to produce phytoequivalent preparations, e.g., specific chemical parameters and/or bioassays to ensure that a preparation can deliver benefits similar to those documented in clinical trials using a particular type of preparation, particularly when such research is being used as a basis for a claim, especially a therapeutic claim.

Botanical Ingredient Review (BIR)

A previous model for an expert herbal panel was the Botanical Ingredient Review (BIR) proposed by the American Herbal Products Association (AHPA) in response to proposed regulations based on NLEA. FDA dismissed this proposal because it was an "industry committee", despite the fact that FDA had relied heavily on other expert panels funded by other industries, namely, the Flavor and Extract Manufacturers Association (FEMA) for the original GRAS list, and the Cosmetics, Toiletries and Fragrances Assocation (CTFA) for information on the safety of new cosmetic ingredients. In fact, the BIR was almost a carbon copy of the Cosmetic Ingredient Review (CIR) developed by CTFA. A widely held perception that FDA was employing a double standard in dismissing the BIR was one of the primary factors that motivated members of the herb industry to promote the passage of DSHEA.

Recommendation of the President's Commission on Dietary Supplement Labels (CDSL)

Recognizing the importance of evaluating the well researched herbs for their possible OTC drug benefits, the President's Commission on Dietary Supplement Labels (CDSL) recommended that FDA establish an expert advisory panel to review herbs for possible OTC drug claims, in its final report in November, 1997. CDSL acknowledged that this recommendation fell outside the domain of the commission's purview of dietary supplements. Nevertheless, CDSL recognized that in other parts of the world, herbs are often regulated as drugs, and that the therapeutic actions of herbal preparations, even when well documented by modern research, cannot be adequately declared on herb product labels or related promotional literature, when these products are sold as dietary supplements under DSHEA. Almost two years has passed since that recommendation, and, to my knowledge, FDA has not responded positively to this recommendation.

American consumers and healthcare practitioners clearly want products with complete labeling of uses and benefits. It is time for FDA to join industry and academia to produce meaningful therapeutic information in this area. Thank you for this opportunity to testify.